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Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

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PROPOSED RE-EVALUATION DECISION

Pendimethalin

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OVERVIEW

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide pendimethalin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing pendimethalin in Canada, provided that the proposed risk-reduction measures are implemented and the data requirements are addressed.

An evaluation of available scientific information found that products containing pendimethalin do not present unacceptable risks to human health, provided that the proposed mitigation measures are implemented. Based on an environmental risk assessment, it was found that pendimethalin can impact non-target terrestrial plants and aquatic organisms through spray drift and surface runoff. However, the observance of buffer zones can effectively mitigate the entry of spray drift into aquatic systems and non-target terrestrial plants.

The PMRA has not made a final determination of the status of pendimethalin under the federal Toxic Substances Management Policy at this time. Additional field data addressing bioaccumulation are required to complete this assessment. In the interim, new environmental risk-reduction measures are proposed for the labels of products containing pendimethalin.

This proposal affects all end-use products containing pendimethalin registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for pendimethalin and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the re-evaluation process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of pendimethalin.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Registration Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products, to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Pendimethalin, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under the Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In its re-evaluation of pendimethalin, the PMRA based its conclusions on these documents taking into account the Canadian use pattern. The PMRA conducted an environmental assessment for pendimethalin, and the federal Toxic Substances Management Policy (TSMP) as well as Regulatory Directive DIR99-03 were taken into consideration during the review. A review of the chemistry of Canadian products was also conducted.

The USEPA conducted a re-evaluation of pendimethalin and conclusions of this re-evaluation are published in a 1997 RED. On the basis of health and environmental risk assessments, the USEPA concluded that pendimethalin was eligible for reregistration with implementation of risk reduction measures. Based on the comparison of the American and Canadian use patterns, the USEPA assessments described in this RED document were considered to be an adequate basis for the Canadian re-evaluation decision with respect to human health. The PMRA's conclusions with respect to the environment and Canadian-specific issues (TSMP) were based on an environmental assessment performed by the PMRA.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Pendimethalin?

Pendimethalin is an agricultural herbicide that is effective against many annual grasses and broadleaf weeds. It is registered for use in Canada on soybeans, dry bulb onions (direct seeded only), field corn, newly planted and established fruit trees (in British Columbia only) including apple, peach, nectarine, cherry and apricot. Formulations registered in Canada include emulsifiable concentrates and water-dispersable granules. It is applied using ground operated boom sprayers. Backpack or low-pressure handwand sprayers could potentially be used in orchards. Application by air is prohibited.

❖ Health Considerations

♦ Can Approved Uses of Pendimethalin Affect Human Health?

Pendimethalin is unlikely to affect your health when used according to the revised label directions.

People can be exposed to pendimethalin by consuming food and water, working as a mixer/loader/handler or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that pendimethalin was unlikely to affect human health, provided that risk-reduction measures were implemented. These conclusions were considered to be applicable to the Canadian situation, and equivalent risk-reduction measures are required.

♦ Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Pendimethalin is currently registered in Canada for use on soybeans, field corn, dry bulb onions (direct seeded only) and fruit trees in British Columbia (apple, peach, nectarine, cherry and apricot). Pendimethalin may be used on other crops in other countries that are imported into Canada. There are no specific Canadian MRLs established for pendimethalin. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as

indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

❖ Environmental Considerations

♦ What Happens When Pendimethalin Is Introduced Into the Environment?

Pendimethalin is toxic to non-target terrestrial plants and aquatic organisms; therefore, additional risk-reduction measures need to be observed.

Pendimethalin can impact non-target terrestrial plants through spray drift, which raises concerns of indirect toxicity to wildlife through adverse effects on habitats. Pendimethalin can enter aquatic ecosystems through spray drift and surface runoff. However, the observance of buffer zones can effectively reduce the entry of spray drift into aquatic systems and non-target terrestrial plants.

The PMRA has taken into account the federal Toxic Substances Management Policy (TSMP) during the review of pendimethalin. Additional data are required.

The PMRA has not made a final determination of the status of pendimethalin under the TSMP at this time. Additional field data addressing bioaccumulation are required to complete this assessment.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of pendimethalin, the PMRA is proposing further risk-reduction measures for product labels.

- **Human Health**
  - To protect mixer/loader/applicators: additional protective equipment.
  - To protect workers re-entering treated sites: a restricted-entry interval.
- **Environment**
  - To reduce potential surface and groundwater contamination as well as to protect non-target sensitive aquatic and terrestrial plants: additional advisory label statements and buffer zones.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrant is required to provide the following data in order to make a final determination of the status of pendimethalin under the TSMP.

- Field data addressing the bioaccumulation of pendimethalin in biota inhabiting the areas of use.

- Analysis of air, water or biota in remote areas (e.g. the Arctic) to determine if long-range transport of pendimethalin is occurring.

Next Steps

Before making a final re-evaluation decision on pendimethalin, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

SCIENCE EVALUATION

1.0 Introduction

Pendimethalin is a selective herbicide used to control broadleaf weeds and grasses in soybeans, dry bulb onions, field corn and fruit trees (in British Columbia only).

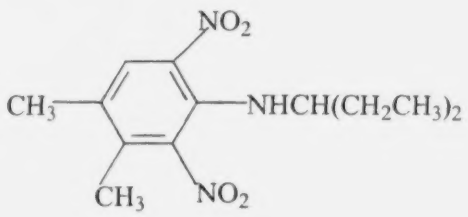
Following the re-evaluation announcement for pendimethalin, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial class end-use products.

The PMRA used an assessment of pendimethalin from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for pendimethalin, dated June 1997, can be referenced for further details. This document as well as other information on the regulatory status of pendimethalin in the United States can be found on the USEPA's website at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Pendimethalin
Function	Herbicide
Chemical class	Dinitroaniline
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	*N*–(1-ethylpropyl)-2,6-dinitro-3,4-xylidine
2 **Chemical Abstracts Service (CAS)**	*N*-(1-ethylpropyl)-3, 4-dimethyl-2,6-dinitrobenzenamine
CAS Number	40487-42-1
Molecular formula	$C_{13}H_{19}N_3O_4$
Structural formula	



Molecular weight	281.3 amu
Purity of the technical grade active ingredients	95% Nominal (lower limit: 92; upper limit: 98), Registration No.21995 98% Nominal (lower limit: 95.1; upper limit: 100), Registration No.27343
Registration numbers	21995 and 27343

Identity of relevant impurities of toxicological, environmental and/or other significance
N-nitrosopendimethalin (CL 94269) is formed in the production process. However, the use of HCl at high temperature (100°C) for 5 hours in the last manufacturing process reduces the *N*-nitrosoamines. The level of *N*-nitrosopendimethalin is below 60 ppm, and the total non-volatile *N*-nitrosamines are below the manufacturing specification of 100 ppm. No volatile *N*-nitrosamines were detected in any of the 5 lots of technical pendimethalin at a limit of detection of 1.0 ppm.

Ethylene dichloride, a process-related solvent, is present at levels of < 0.1%.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	4.0 mPa
Ultraviolet–visible spectrum	λ_{max} = 437 nm (in chloroform) λ_{max} = 239 and 430 nm (in acetone)
Solubility in water at 25°C	0.3 mg/L
n-Octanol–water partition coefficient	log K_{ow} = 5.18
Dissociation constant (p*K*a)	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Pendimethalin is an agricultural herbicide, effective against many annual grasses and broadleaf weeds, registered for use in Canada on soybeans, dry bulb onions (direct seeded only), field corn as well as newly planted and established fruit trees (in British Columbia only), including apple, peach, nectarine, cherry and apricot. Canadian-registered formulations include emulsifiable concentrates and water dispersable granules. The method of application is ground-operated boom sprayers. Backpack or low-pressure handwand sprayers could potentially be used in orchards. Application by air is prohibited.

A comparison of American and Canadian use patterns was conducted. The Canadian formulation type of end-use products and use sites are among those registered in the United States. Application rates for Canadian-registered uses are encompassed by the American application

rates for field corn, soybeans, fruit trees and dry bulb onions in mineral soils, with the exception of dry bulb onions in muck soil, where the Canadian maximum application rate is 3 kg a.i./ha compared to 2.2 kg/ha on dry bulb onions in the United States. However, in the United States, 3 applications per season are allowed (i.e. maximum seasonal application rate of 6.6 kg a.i./ha), whereas, in Canada, only 2 applications are allowed (i.e. seasonal application rate of 6.0 kg a.i./ha). Thus, the seasonal application rate of dry bulb onions in muck soil is encompassed by the American rate. The Canadian potential application methods are among those registered in the United States. Based on this, it was concluded that the USEPA RED for pendimethalin is an adequate basis for the re-evaluation of Canadian uses of pendimethalin.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of pendimethalin. Appendix I lists all pendimethalin products that are registered under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health

In their 1997 RED, the USEPA concluded that the end-use products formulated with pendimethalin met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans if used according to the amended labels of all end-use products containing pendimethalin.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to pendimethalin may occur through consumption of food and water, while working as a mixer/loader/handler or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but measures to mitigate (reduce) risk would be required.

Workers can be exposed to pendimethalin when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Handlers

A number of mixer/loader and application exposure scenarios for handlers were identified based on application methods and equipment used to treat croplands. Among the scenarios assessed in the RED, the following five exposure scenarios were considered to be relevant to the Canadian situation:

1) mixing/loading water dispersable granules for groundboom application;
2) mixing/loading liquid formulations for groundboom application;
3) applying as a spray with groundboom equipment;
4) mixing/loading/applying as a spray with backpack sprayer; and
5) mixing/loading/applying with a low-pressure handwand sprayer.

The USEPA assumed that commercial handlers would have both short- and intermediate-term exposures. Because chronic exposure was not expected, a cancer-risk assessment was not required. With regards to handler exposure, a 70-kg body weight and a dermal absorption factor of 0.10 were assumed. It was assumed that 80 acres per day were treated for groundboom application, and 1 acre per day for backpack or low-pressure handwand spray application. An application rate of 4.5 kg a.i./ha was assumed for all scenarios with the exception of the mixing/loading liquid scenario for which an application rate of 2.25 kg a.i./ha was used. Dermal exposure estimates for all scenarios were obtained from the Pesticide Handlers Exposure Database (PHED), Version 1.1. Inhalation exposure was not required for the three scenarios applicable in Canada, because the inhalation exposure represented less than five percent of the dermal exposure. An MOE of 100 was considered appropriate.

Both short- and intermediate-term exposure for workers performing mixing/loading water dispersable granules for groundboom application and applying pendimethalin as a spray with groundboom equipment, were considered to result in acceptable risk (MOE > 100) when wearing baseline personal protective equipment (PPE) such as a long-sleeve shirt, long pants, shoes and socks. For mixing/loading liquid formulations for groundboom application and for mixing/loading/applying as a spray with either a backpack sprayer or a low-pressure handwand sprayer, the MOE for short- and intermediate-term exposure was acceptable for handlers wearing a single layer of clothing and gloves.

As a result of the handler risk assessment, the USEPA required mixers and loaders of emulsifiable concentrate formulations and mixer/loader/applicator of water-dispersable granules, wettable powders and emulsifiable concentrate formulations to wear long-sleeved shirt and long pants, chemical-resistant gloves and shoes plus socks when using hand-held sprayers.

The USEPA RED adequately addressed potential exposure scenarios associated with the Canadian uses of products containing pendimethalin, and conclusions derived from the RED apply to the Canadian situation. Currently, all Canadian end-use product labels require handlers to wear goggles or a face shield during mixing or loading and to wear chemical-resistant gloves (such as nitrile) and long-sleeved coveralls during mixing, loading, clean-up and repair. In addition, the Canadian emulsifiable concentrate formulation registered for use on field corn, onions and fruit trees as well as the water dispersable granule formulation registered for use on

field corn also require applicators to wear chemical-resistant gloves and long-sleeved coveralls. These PPE requirements currently on the labels are considered to be adequate; however, there are no PPE requirements indicated for applicators of pendimethalin to soybeans. Based on this, the PMRA requires long pants and a long-sleeved shirt during application of pendimethalin to soybeans to further protect workers. Additional instructions concerning good hygiene practices are also required on labels. The proposed label amendments are listed in Appendix II.

3.1.1.2 Postapplication Exposure and Risk

No chemical-specific postapplication studies were available; therefore, surrogate data on dislodgeable foliar residues (DFRs) for five different chemicals on turf were used by the USEPA to assess postapplication exposure to pendimethalin. The USEPA established three worst-case exposure scenarios that were considered to be representative of all pendimethalin postapplication scenarios (postapplication exposure to workers harvesting turfgrass from sod farms, golf-course maintenance workers and toddlers on residential turf). The only scenario applicable to Canada is the postapplication exposure to workers harvesting turfgrass from sod farms. This was considered representative of worst-case postapplication exposures to other agricultural workers following pendimethalin applications to commercial or research food, feed, fibre, ornamental, forestry and turf crops.

A transfer coefficient of 10 000 cm^2/hour was based on the USEPA's best estimate of harvesting sod. Surrogate pendimethalin DFR data were chosen as the best available data for the sod farm turf scenario. These data represented an application rate of 2 lb a.i./acre (2.24 kg a.i./ha), but the DFR data were normalized to represent the maximum application rate for sod farm turf of 3 lb a.i./acre (3.36 kg a.i./ha). The MOEs for the sod farm scenario (2 hours, 1 day, 2 days and 3 days after treatment) were all adequate (> 100). However, because the assessment was based on surrogate, non-guideline data, an interim restricted-entry interval (REI) of 24 hours was established pending submission of chemical-specific postapplication studies to further refine the risk estimates. The 24-hour REI was applicable to pendimethalin use on all food, feed, fibre, ornamental, forestry and turfgrass crops grown for commercial or research purposes, with the exception of products that were soil-injected or soil-incorporated if there were to be no contact with anything that had been treated upon re-entry.

Postapplication activities associated with pendimethalin use on agricultural crops are expected to be similar between the United States and Canada. The transfer coefficient of 10 000 cm^2/hour used by the USEPA encompasses the postapplication scenarios for onion (loop and true 2-leaf stage) and corn (up to 4-leaf stage). Based on this, the PMRA recommends a 24-hour REI for field corn and dry bulb onions to further protect workers from postapplication exposure. However, based on the method and timing of application, an REI is not required for soybeans and for fruit trees in Canada because pendimethalin is incorporated into the soil 45 days before planting for soybeans and applied pre-emergent to weed growth to the ground around the fruit trees. Therefore, there is no potential for foliar contact, and postapplication exposure is expected to be negligible. The proposed label amendments are listed in Appendix II.

3.1.2 Aggregate Exposure and Risk Assessment

3.1.2.1 Exposure From Food

No acute toxicological endpoint was identified, and no acute dietary assessment was conducted. Pendimethalin was classified as a possible human carcinogen based on thyroid follicular cell adenomas in male and female rats, which were hypothesized to be due to a thyroid-pituitary imbalance. Both chronic cancer and non-cancer risks were evaluated by the USEPA using the reference dose (RfD) approach. Chronic dietary exposure assessment was conducted using the Dietary Risk Evaluation System. A theoretical maximum residue contribution (TMRC) was used to estimate dietary exposure. TMRC assumed residues on foods were at tolerance levels and that 100% of each crop registered for pendimethalin was treated. Food consumption estimates came from the United States Department of Agriculture Food Consumption Survey (1977–1978). The TMRC exposure estimates for both the overall population in the United States and various population subgroups were then compared to the RfD of 0.1 mg/kg bw/day. Chronic exposure to pendimethalin was estimated by the USEPA to be < 1% RfD for the overall population in the United States and < 2% RfD for the most highly exposed subgroup (non-nursing infants). Both chronic cancer and non-cancer dietary risks due to food were considered to be minimal.

The assessment addressed uses on corn, soybeans and dry bulb onions, which are the same food/feed crops registered in Canada with one exception. In Canada, pendimethalin can be applied to the soil, pre-emergent to weed growth, around established fruit trees (apple, peach, nectarine, cherry and apricot), whereas in the United States, pendimethalin is used around non-bearing fruit trees and is therefore not considered a food use for those commodities (i.e. no tolerances exist in the United States for apple, peach, nectarine, cherry and apricot). Despite this difference in use pattern, the assessment conducted by the USEPA is considered to be relevant to Canada because it was based on a conservative Tier I assessment of exposure from food, using tolerance levels and the assumption that 100% of the crop was treated. The American tolerances for corn, soybeans and dry bulb onions used in the risk assessment were equal to Canadian MRLs (0.1 ppm). The chronic dietary exposure to pendimethalin was estimated by the USEPA to be < 2% RfD for the most highly exposed subgroup (non-nursing infants) and < 2% RfD for drinking water (see Section 3.1.2.2); therefore, there was adequate room (96%) remaining in the risk cup. There are no MRLs established for pendimethalin residues. Consequently, in Canada, residues of pendimethalin in all commodities must not exceed the default of 0.1 ppm[3]. The USEPA assessment is considered applicable for the Canadian situation.

3.1.2.2 Exposure From Drinking Water

The USEPA reported that pendimethalin had been detected in groundwater in limited areas of two States at concentrations of 0.2 to 0.9 ppb. The maximum concentration of pendimethalin detected in surface water was 18 ppb (from a surface water sample collected in Ohio).

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[3] Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

Based on the maximum surface water monitoring value of 18 ppb, a 10-kg child consuming 1 L of drinking water and a toxicity endpoint of 10 mg/kg bw/day (from a 14-day thyroid function study), chronic dietary risk from water was estimated to be < 2% of the RfD for all population subgroups, including the most highly exposed subgroup.

This worst-case scenario is considered applicable for the Canadian situation because pendimethalin application rates in Canada are encompassed by application rates used in the United States.

3.1.2.3 Aggregate Risk Assessment

The USEPA included chronic dietary exposure due to food and water and short-term residential exposure for their aggregate risk assessment. Because residential exposure is not applicable to the Canadian use pattern of pendimethalin, only the assessment of aggregate exposure due to food and water is reported here. Chronic dietary exposure to pendimethalin was estimated to be < 2% RfD for the most highly exposed subgroup (non-nursing infants), and chronic exposure due to water was estimated to be < 2% RfD for all population subgroups. Therefore, the aggregate risk estimate for chronic food plus water exposure was calculated as < 4% RfD, which did not exceed the USEPA's level of concern.

The Canadian potential aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment; therefore, the aggregate exposure conclusions are considered applicable to the Canadian uses of pendimethalin.

3.1.3 Cumulative Effects

The USEPA has not determined whether pendimethalin has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that pendimethalin does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

4.0 Impact on the Environment

4.1 Environmental Fate

The reported solubility of pendimethalin in water is 0.275 mg/L at 25°C, which would classify it as sparingly soluble. From the reported vapour pressure (9.4×10^{-6} mm Hg at 25°C), pendimethalin would be classified as relatively non-volatile under field conditions, according to Kennedy and Talbert (1977). The Henry's law constant of 1.26×10^{-5} atm.m^3.mol^{-1} indicates that pendimethalin has a potential to volatilize from moist soil and water. Volatility can be significant under warm, moist soil conditions. Volatilization of pendimethalin from pond water samples is a major means of dissipation. Pendimethalin was detected frequently (> 80%) in rain samples from Ontario in 2004 (Environment Canada 2005). The octanol/water partition coefficient (log K_{ow}) was reported to be 5.18, which indicates that pendimethalin has a high potential for bioaccumulation in biota.

Pendimethalin is stable to hydrolysis at environmentally relevant pHs (pH 5 to pH 9). Phototransformation of pendimethalin is not an important route of transformation on soil or in water. No information is available addressing the phototransformation of pendimethalin in air.

Biotransformation is a route of transformation for pendimethalin in soil under aerobic conditions although transformation is slow. Pendimethalin would be considered moderately persistent in soil under aerobic conditions in the laboratory according to the classification scheme of Goring et al. (1975). Pendimethalin is stable to anaerobic soil biotransformation. Biotransformation is not an important route of transformation in water; however, it is a route of transformation for residues bound to sediments.

Pendimethalin is strongly adsorbed and is immobile in soils. Adsorption is positively correlated with the percentage of organic carbon.

In field studies presented in Table 4.1.1, pendimethalin was found to be persistent (DT50 257– > 400 days) in Ontario muck soil, loam soils from Georgetown (Ontario) and Lethbridge (Alberta), a sandy loam soil from Carman (Manitoba) and a silty clay loam soil from Ellerslie (Alberta). There is a high possibility of residue carryover and accumulation occurring as a result of repeated annual application. The majority of the pendimethalin residues remained in the 0–7.5 cm layer of the various soils and no downward movement was evident indicating that the potential for leaching is minimal.

Table 4.1.1 Canadian Soil Field Dissipation Studies Using Pendimethalin

Location	Soil Type/Properties	Type/Timing of Application	DT_{50}
Thedford-Grand Bend marsh Ontario	Muck soil (properties not provided)	Soil surface, early postemergence	297 days
Georgetown, Ontario	Loam, 32% sand, 49% silt, 18% clay, 4.0% organic matter, pH 7.0	Soil incorporated, preplant	273 days
		Soil surface, pre-emergence	257 days
Lethbridge, Alberta	Loam, 3.1% organic matter, pH 6.9	Soil surface, preplant	350 days
Carman, Manitoba	Sandy loam, 1.9% organic matter, pH 5.7	Soil surface, preplant	> 400 days
Ellerslie, Alberta	Silty clay loam, 7.4% organic matter, pH 6.5	Soil incorporated, preplant	> 400 days

4.2 Environmental Toxicology

4.2.1 Terrestrial

The no observed effect concentration (NOEC) for the earthworm *Eisenia foetida* using Stomp 330E (the European formulation of Prowl), which is guaranteed to contain pendimethalin at 330 g/L was determined as 3.4 mg a.i./kg soil. The median lethal dose (LD_{50}) was > 49.7 µg/bee for a honeybee acute contact study using the technical grade of the active ingredient for pendimethalin. The acute oral LD_{50} of pendimethalin to the mallard duck (*Anas platyrhynchos*) was 1421 mg a.i./kg bw. The acute dietary median lethal concentration (LC_{50}) of pendimethalin to birds ranges from 4187 mg a.i./kg diet for the bobwhite quail (*Colinus virginianus*) to 4640 mg a.i./kg diet for the mallard duck (*A. platyrhynchos*). The rat acute oral LD_{50} is 1050 mg a.i./kg bw for female rats and 1250 mg a.i./kg bw for male rats. A two-generation rat reproduction study reported a reproductive no observed effect level (NOEL) of 2500 mg a.i./kg diet. Results of the non-target terrestrial plant seedling emergence toxicity testing indicate an effect concentration at 25% (EC_{25}) of 33.6 g a.i./ha for ryegrass, which was the most sensitive species tested. Results of the non-target terrestrial plant vegetative vigour toxicity testing indicate an EC_{25} of 39.2 g a.i./ha for ryegrass, which was the most sensitive species tested.

4.2.2 Aquatic

Technical pendimethalin is acutely toxic (96-h LC_{50} 33 µg a.i./L) to freshwater aquatic invertebrates. In aquatic invertebrates, reproductive impairment may occur at levels greater than 14.5 µg a.i./L. Technical pendimethalin is also acutely toxic (96-h LC_{50} 138–418 µg a.i./L) to freshwater fish. Reproductive effects to freshwater fish may occur at levels greater than 6.3 µg a.i./L. Detrimental effects to the growth and reproduction of freshwater algae may occur at levels greater than 3.0 µg a.i./L. Detrimental effects to the growth and reproduction of freshwater vascular plants (*Lemna sp.*) occur at levels greater than 5.6 µg a.i./L. Acute toxicity of pendimethalin ranges from 96-h LC_{50} 210–1600 µg a.i./L for estuarine/marine invertebrates and has a 96-h LC_{50} of 707 µg a.i./L for estuarine/marine fish. Detrimental effects to the growth and reproduction of estuarine/marine algae may occur at levels greater than 0.7 µg a.i./L.

The terrestrial and aquatic environmental toxicology endpoints are summarized in Table 4.2.1.

Table 4.2.1 Summary of Environmental Toxicology Endpoints

Species	% a.i.	Toxicity Endpoint
Earthworm, *Eisenia foetida*	Stomp 330E pendimethalin	14-d NOEC 3.4 mg a.i./kg soil
Honeybee, *Apis mellifera*	Technical	Acute contact LD_{50} > 49.7 µg/bee
Mallard duck, *Anas platyrhynchos*	Technical	Acute oral LD_{50} 1421 mg a.i./kg bw

Species	% a.i.	Toxicity Endpoint
Bobwhite quail, *Colinus virginianus*	Technical	Acute dietary LC_{50} 4187 mg a.i./kg diet
Mallard duck, *Anas platyrhynchos*	Technical	Acute dietary LC_{50} 4640 mg a.i./kg diet
Rat, *Rattus norvegicus* - female - male	Technical	Acute oral LD_{50} 1050 mg a.i./kg bw Acute oral LD_{50} 1250 mg a.i./kg bw Reproductive NOEL 2500 mg a.i./kg diet
Ryegrass, *Lolium perenne L.*	93%	Seedling emergence EC_{25} 33.6 g a.i./ha
Ryegrass, *Lolium perenne L*	93%	Vegetative vigour EC_{25} 39.2 g a.i./ha
Waterflea, *Daphnia magna*	Technical 92%	96-h LC_{50} 33 µg a.i./L 21-d NOEC 14.5 µg a.i./L
Rainbow trout, *Oncorhynchus mykiss*	93%	96-h LC_{50} 138 µg a.i./L
Bluegill sunfish, *Lepomis macrochirus*	93%	96-h LC_{50} 199 µg a.i./L
Channel catfish, *Ictalurus punctatus*	93%	96-h LC_{50} 418 µg a.i./L
Fathead minnow, *Pimephales promelas*	98%	28-d NOEC 6.3 µg a.i./L
Green algae, *Selenastrum capricornutum*	93%	96-h NOEC 3.0 µg a.i./L
Duckweed, *Lemna gibba*	93%	96-h NOEC 5.6 µg a.i./L
Eastern oyster (embryo-larvae), *Crassostrea virginica*	93%	96-h LC_{50} 210 µg a.i./L
Pink shrimp, *Penaeus duorarum*	93%	96-h LC_{50} 1600 µg a.i./L
Sheepshead minnow, *Cyprinodon variegatus*	93%	96-h LC_{50} 707 µg a.i./L
Estuarine/marine diatom, *Skeletonema costatum*	93%	96-h NOEC 0.7 µg a.i./L

4.3 Terrestrial Assessment

An initial deterministic terrestrial risk assessment was conducted for pendimethalin. In this assessment, risk was characterized by the quotient method, calculated as the ratio of the estimated environmental concentration to the effects endpoints of concern. Risk quotient (RQ) values less than one are considered indicative of a low risk to non-target organisms, whereas values greater than one are considered to indicate that some degree of risk exists for non-target organisms. The endpoint used for both acute and chronic toxicity is the NOEC from the appropriate laboratory study or, if not available, $1/10^{th}$ of the appropriate LD_{50} or LC_{50} value.

Earthworms are considered to be at negligible risk (RQ = 0.01–0.04) for all applications of pendimethalin. Pendimethalin is also not expected to be a risk to bees following all registered applications.

Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994) were used to determine the risk to birds and small wild mammals due to the consumption of contaminated food items.

Large birds are not expected to be at risk from the consumption of contaminated food following all single applications of pendimethalin on field corn, soybeans, dry bulb onions or fruit trees because it would require greater than one day of continuous feeding to reach the NOEL and LD_{50}. Smaller bird species such as the American robin and field sparrow required about 6 hours of continuous feeding to reach the NOEL and 4.5 days of continuous feeding to reach the LD_{50} following the highest application rate (2 applications of 3000 g a.i./ha on dry bulb onions). The estimated NOEL has a large degree of uncertainty associated with it compared to the LD_{50}; therefore, the threshold of effects would likely not be reached from the consumption of contaminated food items in a single day. Birds, therefore, are not expected to be at acute risk from the consumption of contaminated food following all registered applications of pendimethalin.

Small birds would need to consume about 46% of their diet contaminated with pendimethalin to reach an RQ = 1, following the highest application rate (2 applications of 3000 g a.i./ha) which is unlikely.

The number of hours of continuous feeding by a small wild mammal on a contaminated diet to reach the NOEL ranges from 2.4 to 13 for all of the registered applications of pendimethalin. The number of days of continuous feeding on a contaminated diet to reach the LD_{50} ranges from 2 to 11 for all of the registered applications of pendimethalin. The estimated NOEL has a large degree of uncertainty associated with it compared to the LD_{50}; therefore, the threshold of effects would likely not be reached from the consumption of contaminated food items in a single day. Small wild mammals, therefore, are not expected to be at acute risk due to the consumption of contaminated food items following all of the registered applications of pendimethalin.

The risk to small wild mammals from exposure to pendimethalin on a chronic reproductive basis was low (RQ = 0.2–0.5) for all single applications and 2 applications at 1500 g a.i./ha and moderate (RQ = 1.1) for 2 applications at 3000 g a.i./ha. At the highest application rate on dry bulb onions (2 × 3000 g a.i./ha), 91% of the diet contaminated with pendimethalin would be required to reach an RQ = 1, which is highly unlikely. Therefore, small wild mammals are not expected to be at chronic risk following all registered applications of pendimethalin.

The spray drift data of Wolfe and Caldwell (2001) was used to determine that the 90th percentile deposit onto non-target terrestrial plants adjacent to a field sprayed using groundboom equipment will not exceed 10% of the application rate. This information was used to recalculate the estimated environmental concentrations (EECs) to determine the risk to terrestrial plants adjacent to a field sprayed using groundboom equipment. The most sensitive terrestrial plant endpoint (seedling emergence for ryegrass EC_{25} = 33.6 g a.i./ha) was used for the risk assessment. Based on the limited data on toxicity to non-target terrestrial plants, there is a moderate to high risk (RQ = 32–174) to non-target terrestrial plants in areas adjacent to treated fields from drift following applications of pendimethalin.

4.4 Aquatic Assessment

Aquatic organisms may be exposed to residues of pendimethalin initially from drift immediately following ground application and subsequently from runoff following rainfall events. The risk assessment for aquatic organisms was designed to characterize the risk from drift and runoff separately so that appropriate mitigative measures may be used to reduce risk from both sources of exposure. A refined aquatic risk assessment was conducted beginning with a screening level assessment.

4.4.1 Screening Level Assessment

The initial aquatic assessment conducted is a deterministic screening level risk assessment. This approach is conservative and primarily designed to identify the taxonomic groups that are not at risk and/or the use scenarios that do not pose an unacceptable risk. The screening level EEC is a conservative exposure estimate determined as the concentration resulting from a direct application to a 30-cm depth of water. The endpoint used for both acute and chronic toxicity is the NOEC from the appropriate laboratory study, or if not available, 1/10th of the appropriate LC_{50} value. If the RQ from this analysis is < 1, then it can be concluded there is low risk and no further refinement is necessary. The RQs for all of the freshwater and estuarine/marine taxa for all applications of pendimethalin are > 1, indicating further refinement is necessary.

4.4.2 Drift

As with the terrestrial assessment, the spray drift data of Wolfe and Caldwell (2001) were used to determine that the 90th percentile deposit into an aquatic habitat adjacent to a field sprayed using groundboom equipment will not exceed 10% of the application rate. This information was used to determine exposure from drift in a 80-cm deep water body adjacent to applications of pendimethalin made by groundboom equipment. The toxicology endpoints used to calculate risk quotients were the same as those used in the screening level assessment.

Pelagic freshwater aquatic invertebrates inhabiting shallow water bodies adjacent to the site of application are at moderate to high risk (RQ = 4.2–14.2) of acute effects and at low to moderate risk (RQ = 1.0–3.2) of chronic effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers.

Freshwater fish inhabiting shallow water bodies adjacent to the site of application are at moderate risk (RQ = 1.1–3.4) of acute effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers and at moderate risk (RQ = 2.2–7.5) of chronic effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers.

Freshwater algae inhabiting shallow water bodies adjacent to the site of application are at moderate risk (RQ = 4.7–7.0) of chronic effects from exposure to concentrations of pendimethalin from drift following all single applications and multiple applications at 1500 g a.i./ha and at high risk (RQ = 15.7) of chronic effects following multiple applications at 3000 g a.i./ha with groundboom sprayers.

Freshwater vascular plants inhabiting shallow water bodies adjacent to the site of application are at moderate risk (RQ = 2.5–8.4) of acute effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers.

Estuarine/marine invertebrates inhabiting shallow water bodies adjacent to the site of application are at low risk (RQ = 0.7–1.0) of acute effects from exposure to concentrations of pendimethalin from drift following all single applications and at moderate risk (RQ = 1.2–2.2) of acute effects following all multiple applications with groundboom sprayers.

Estuarine/marine fish inhabiting shallow water bodies adjacent to the site of application are at low risk (RQ = 0.2–0.6) of acute effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers.

Estuarine/marine algae inhabiting shallow water bodies adjacent to the site of application are at high risk (RQ = 20–67) of chronic effects from exposure to concentrations of pendimethalin from drift following applications at all rates with groundboom sprayers.

4.4.3 Runoff

The linked models PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) were used to predict the EECs resulting from runoff of pendimethalin following application. The PRZM simulates runoff and erosion events from an agricultural field that are then input into EXAMS to simulate the fate in the receiving water ecosystem. As defined, this scenario was designed to represent concentrations that would occur in shallow bodies of water and/or headwater streams next to the site of application.

Simulations were run for three crop scenarios: field corn in Ontario/Quebec; fruit trees in British Columbia; and dry bulb onions. The application rates for pendimethalin on these crops differ substantially from 1.68 kg a.i./ha/year on fruit trees and corn (1 × 1.68 kg a.i./ha) to

6 kg a.i./ha/year on onions (2 × 3 kg a.i./ha, at 14-day intervals). Two geographic scenarios were simulated for corn (corn in Ontario and Quebec), one for fruit trees in British Columbia (apples) and one for dry bulb onions (onions in Ontario, from Ontario-corn scenario with organic carbon modified to 50% to reflect approximately 80% organic matter). The model was run to simulate 20 years of applications for all scenarios. The dates of application used ranged from 25 April to 13 June for corn; from 4 April to 13 June for apples; and from 1 May to 25 May for onions.

For each year of the simulation, the PRZM/EXAMS calculates both peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over 5 time periods (96-hour, 21-day, 60-day, 90-day and 1 year). The 90th percentiles of the peak and the time-averaged concentrations (µg/L) are used in the risk assessment. The EEC's with the appropriate time periods were used to calculate the RQs, e.g. 96-hour for acute endpoints and 21-day for chronic endpoints. The toxicology endpoints used to calculate risk quotients were the same as those used in the screening level and refined drift assessments.

Freshwater invertebrates inhabiting shallow water bodies adjacent to the site of application are at negligible risk (RQ = 0.04) of acute effects from exposure to concentrations of pendimethalin from runoff following applications to fruit trees in British Columbia and at low risk (RQ = 0.2–0.4) of acute effects following applications on corn and soybeans in Ontario and Quebec, and onions in Ontario. Freshwater invertebrates are at negligible risk (RQ = 0.003–0.04) of chronic effects from exposure to concentrations of pendimethalin from runoff following all applications including fruit trees in British Columbia, corn and soybeans in Ontario and Quebec, and onions in Ontario.

Freshwater fish inhabiting shallow water bodies adjacent to the site of application are at negligible risk (RQ = 0.006–0.09) of both acute and chronic effects from exposure to concentrations of pendimethalin from runoff following all applications including fruit trees in British Columbia, corn and soybeans in Ontario and Quebec, and onions in Ontario.

Freshwater algae and vascular plants inhabiting shallow water bodies adjacent to the site of application are at negligible risk (RQ = 0.02–0.04) of effects from exposure to concentrations of pendimethalin from runoff following applications to fruit trees in British Columbia and at low risk (RQ = 0.1–0.4) of effects following applications on corn and soybeans in Ontario and Quebec, and onions in Ontario.

Estuarine/marine invertebrates and fish inhabiting shallow water bodies adjacent to the site of application are at negligible risk (RQ = 0.002–0.006) of acute effects from exposure to concentrations of pendimethalin from runoff following applications on fruit trees in British Columbia, which is the only Canadian use pattern that could result in exposure to estuarine/marine organisms.

Estuarine/marine algae inhabiting shallow water bodies adjacent to the site of application are at low risk (RQ = 0.2) of chronic effects from exposure to concentrations of pendimethalin from runoff following applications on fruit trees in British Columbia, which is the only Canadian use pattern that could result in exposure to estuarine/marine organisms.

4.5 Risk Mitigation

Pendimethalin can impact non-target terrestrial plants through spray drift, which raises concerns of indirect toxicity to wildlife through adverse effects on habitats. The observance of buffer zones can effectively mitigate the entry of spray drift onto non-target terrestrial plants. The spray drift data of Wolfe and Caldwell (2001) were used for predicting the spray drift from groundboom sprayers. Based on this data and the most sensitive terrestrial plant endpoint (seedling emergence for ryegrass EC_{25} = 33.6 g a.i./ha), buffer zones were determined for mitigating the entry of spray drift onto terrestrial non-target plants (Appendix II). In addition, the buffer zone estimation was based on the maximum application rate, the number of applications per season and the interval between applications.

Pendimethalin can enter aquatic ecosystems through spray drift and surface runoff. The observance of buffer zones can effectively mitigate the entry of spray drift into aquatic systems. Based on the spray drift data of Wolfe and Caldwell (2001) and the most appropriate freshwater and estuarine/marine aquatic organism endpoints, buffer zones were determined for mitigating the entry of spray drift into aquatic systems (Appendix II). In addition, the buffer zone estimation was based on the maximum application rate, maximum number of applications per season and the maximum interval between applications.

4.6 Toxic Substances Management Policy Considerations

The PMRA has taken into account the federal Toxic Substances Management Policy (TSMP) during the review of pendimethalin. The four criteria against which pendimethalin has been assessed are: predominantly anthropogenic (source); persistence; bioaccumulation; and *Canadian Environmental Protection Act* for CEPA-toxic or CEPA-equivalent.

By definition, the majority of chemical pesticides are considered as arising from anthropogenic sources as they are manufactured and applied to the environment for pest control purposes. As such, pendimethalin is considered to have met the criteria of being predominately anthropogenic.

Pendimethalin was observed to have DT_{50}s of 257 to > 400 days in soils from various Canadian locations exceeding the TSMP persistence criteria of ≥ 6 months.

Pendimethalin has a log K_{ow} of 5.18 and a bioconcentration factor (BCF) of 5100 in bluegill sunfish which exceeds the TSMP criteria for log K_{ow} of ≥ 5 and bioconcentration of ≥ 5000. However, in a laboratory fish bioconcentration study, depuration was rapid with 87–91% of the residues eliminated from the fish tissues by 14 days of depuration. In a metabolism study conducted with rats, about 70% of the radioactivity was excreted in the feces and 20% in the urine within 24 hours. Muir (2006) observed bioaccumulation factors (BAFs) for pendimethalin ranging from 174 to 26 233 in zooplankton from 3 lakes located in southwestern and north/central Ontario sampled in 2003 and 2004. There is considerable uncertainty, associated with these values due to variation of pendimethalin concentrations in water and zooplankton observed on different sampling dates. Additional field data addressing bioaccumulation in biota are required (see Section 6.0).

Based on an environmental risk assessment, pendimethalin was found to be entering the environment at levels that pose a risk to terrestrial non-target plants and aquatic organisms and would therefore be considered "CEPA-toxic equivalent" under the *Canadian Environmental Protection Act*.

The PMRA has not made a final determination of the status of pendimethalin under the TSMP at this time. Additional field data addressing bioaccumulation are required to complete this assessment.

5.0 Proposed Re-evaluation Actions

The PMRA has determined that the risk to human health associated with the use of pendimethalin is acceptable with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health. Based on an environmental risk assessment, it was found that pendimethalin can impact non-target terrestrial plants and aquatic organisms through spray drift and surface runoff. Further risk-reduction measures are proposed to reduce potential surface and groundwater contamination and protect non-target sensitive aquatic and terrestrial plants.

The PMRA has taken into account the federal Toxic Substances Management Policy during the review of pendimethalin. However, a final determination of the status of pendimethalin under the TSMP cannot be made at this time. Additional field data addressing bioaccumulation are required to complete this assessment.

Canadian end-use product labels should be amended to include label statements listed in Appendix II. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

6.0 Data Required as Condition for Continued Registration

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrant of this active ingredient is required to provide these data within the timeline specified in the decision letter that the PMRA will send to the registrant of the technical active ingredient.

- Field data addressing the bioaccumulation of pendimethalin in biota inhabiting the areas of use.

- Analysis of air, water, or biota in remote areas (e.g. the Arctic) to determine if long range transport of pendimethalin is occurring.

These data will be used to make a final determination of the status of pendimethalin under the TSMP.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for pendimethalin is available at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram
a.i.	active ingredient
amu	atomic mass unit
ASABE	American Society of Agricultural and Biological Engineers
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetre
DACO	data code
DFR	dislodgeable foliar residue
DT_{50}	dissipation time at 50%
EC_{25}	effect concentration at 25%
EEC	estimated environmental concentration
EXAMS	Exposure Analysis Modeling System
FQPA	*Food Quality Protection Act*
g	gram
ha	hectare
HCl	hydrochloric acid
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*-octanol–water partition coefficient
L	litre
lb	pound
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
m	metre
mg	milligram
MOE	margin of exposure
mm	millimetre
mm Hg	millimetre mercury
mPa	millimetre Pascal
MRL	maximum residue limit
NOEC	no observed effect concentration
NOEL	no observed effect level
PHED	Pesticide Handlers Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
RED	Reregistration Eligibility Decision
REI	restricted-entry interval

RfD	reference dose
RQ	risk quotient
TMRC	theoretical maximum residue contribution
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Products Containing Pendimethalin Registered in Canada as of January 2007

Product Name	Registrant	Registration Number	Guarantee	Class
AC 92553 Technical Herbicide	BASF Canada Inc.	21995	95%	Technical
AC 92553 Technical Herbicide		27343	98%	Technical
PROWL 60 WDG Herbicide		25137	60%	Commercial
PROWL 400 EC Herbicide		23439	400g/L	Commercial
VALOR Herbicide[a]		24269	320g/L	Commercial
VALOR-1 Herbicide[b]		27458	300.22 g/L	Commercial

[a] Valor herbicide, Registration No. 24269, is a combination of pendimethalin and imazethapyr (22 g/L). This product will be discontinued on 31 December 2007, and the registration will expire on 31 December 2010.

[b] Valor-1 herbicide, Registration Number 27458, is a combination of pendimethalin and imazethapyr (24.61 g/L).

Appendix II Label Amendments for Products Containing Pendimethalin

Label Amendments Relating to Human Health

Canadian end-use product labels should be amended to include the following statements to further protect workers.

For pendimethalin end-use products registered for use on soybeans, the following statement must be included in a section entitled **PRECAUTIONS**:

"Applicators must wear long pants and a long-sleeved shirt during application."

For all commercial end-use products containing pendimethalin, the following statements must be included in a section entitled **PRECAUTIONS**:

- "It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application."
- "Users should wash hands before eating, drinking, chewing gum and when using tobacco or the toilet."
- "Remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash hands (or any other skin that came into contact with the product) with soap and water and change into clean clothing."
- "Remove clothing/personal protective equipment immediately if pesticide comes in contact with the skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing before reuse."
- "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not re-use them."
- "If this pest control product is to be used on a commodity that may be exported to the United States and you require information on acceptable residue levels in the United States, contact 1-866-375-4648 or www.cropro.org/."

For those end-use products that are registered for use on field corn and/or dry bulb onions, the following statement must be included in a section entitled **DIRECTIONS FOR USE**:

"Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours."

Label Amendments Relating to the Environment

The following additional label statements are required further protect the environment.

Add to ENVIRONMENTAL HAZARDS:

"TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."

Add to DIRECTIONS FOR USE:

"DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats."

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

"Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural and Biological Engineers (ASABE) medium classification."

"DO NOT apply by air."

"Buffer Zones

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:						
		Freshwater Habitats of Depths:			Estuarine/Marine Habitats of Depths:			Terrestrial Habitat
		Less than 1 m	1–3 m	Greater than 3 m	Less than 1 m	1–3 m	Greater than 3 m	
Field sprayer*	Dry bulb onions (muck soils)	15	5	2	40	15	5	5
	Soybeans	5	2	1	15	5	2	2
	Field corn	5	2	1	20	10	3	2

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:						
		Freshwater Habitats of Depths:			Estuarine/Marine Habitats of Depths:			Terrestrial Habitat
		Less than 1 m	1–3 m	Greater than 3 m	Less than 1 m	1–3 m	Greater than 3 m	
	Dry bulb onions (mineral soil Western Canada)	5	2	1	20	5	3	2
	Dry bulb onions (mineral soil Eastern Canada)	5	3	1	25	10	4	4

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%."

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

References

A list of additional information used in the environmental assessment for pendimethalin is included below. This is limited to a subset of published documents. It is not an exhaustive listing of all published studies on pendimethalin. This list does not include references to any unpublished proprietary data used in this assessment.

Environment Canada. 2005. *Presence, Levels and Relative Risks of Priority Pesticides in Selected Canadian Aquatic Ecosystems*. An Environment Canada Pesticides Science Fund Project. Project Progress Progress Report for 2005. National Water Research Institute, Environment Canada, Ottawa. 82 p.

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